

IN THE UNITED STATES
PATENT AND TRADEMARK OFFICE

APPELLANTS' REPLY BRIEF

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
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IN THE UNITED STATES
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Appellants: Grooms, *et al.*)
Serial No.: 09/905,683)
Filed: July 13, 2001)
For: "Multi-Component Cortical Bone)
Assembled Implant")
(Title As Amended))
Group Art Unit: 3738)
Examiner: Bruce Edward Snow)
)

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Dear Sir:

In response to the Examiner's Answer of March 11, 2008, the Appellants hereby file this Reply Brief. The Appellants respectfully request that the Board of Patent Appeals and Interferences reverse the pending rejections of claims 111-118 and 120-136 of the present application.

I. STATUS OF THE CLAIMS

In the present application, claims 111-118 and 120-136 are pending and have been twice rejected. All presented amendments to these claims have been entered. Claims 111-118 and 120-136 as currently pending are presented for consideration on appeal. The text of pending claims 111-

118 and 120-136 was attached in the Claims Appendix submitted with Appellants' Brief filed March 12, 2007.

II. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. Whether the Examiner erred in rejecting claims 111-118, 120-123, and 129-136 under 35 U.S.C. §102(b) in view of Fred H. Albee, "Bone Surgery With Machine Tools," *Scientific American*, Vol. 154, No. 4, pp. 178-181 (1936),¹ (hereinafter the "Albee" reference).

2. Whether the Examiner erred in rejecting claims 111-118 and 120-136 under 35 U.S.C. §103(a) over U.S. Pat. No. 5,989,289 (hereinafter the "Coates" reference)² in view of European Patent Application No. 0517030 (hereinafter the "Siebels" reference).³

3. Whether the Examiner erred in rejecting claims 111-118 and 120-136 under 35 U.S.C. §103(a) over U.S. Pat. No. 5,192,327 (hereinafter the "Brantigan" reference)⁴ in view of the Coates reference.

III. ARGUMENT

Applicant will focus this reply on new points raised in the Examiner's Answer and specific points that would benefit from clarification. Applicant has endeavored to avoid repeating points made in Appellant's Opening Brief, but it is to be understood that all points made in that Brief are reasserted and are not waived.

A. The Albee Reference Does Not Anticipate the Pending Claims, and the Rejection Under 35 U.S.C. §102(b) Should Be Withdrawn

1. The Albee Reference Does Not Anticipate Pending Claim 111

Pending claim 111 is directed to an assembled bone implant comprising first and second cortical bone portions connected by receiving pins inserted into circular through holes.⁵ The

¹ Exhibit 17, Evidence Appendix submitted with Appellants' Brief filed March 12, 2007.

² Exhibit 18, Evidence Appendix submitted with Appellants' Brief filed March 12, 2007.

³ Exhibit 19, Evidence Appendix submitted with Appellants' Brief filed March 12, 2007.

⁴ Exhibit 20, Evidence Appendix submitted with Appellants' Brief filed March 12, 2007.

⁵ Claim 111, Claims Appendix submitted with Appellants' Brief filed March 12, 2007.

Albee reference does not teach circular through holes or retention pins for connecting the first cortical bone portion to the second cortical bone portion as recited in claim 111.⁶

In concluding that the Albee reference discloses these elements, the Examiner has provided the following assertions:

Albee teaches using “round dowels” (or pins) (see Editor’s box starting on page 178 and ending on page 179) for reconnecting broken bones; see at least figures 10, 4, 1, 2a showing the use of dowels.⁷

Claim 111 does not discuss round dowels or reconnecting bones. Claim 111 involves a retention pin connecting first and second cortical bone portions of an assembled implant. None of sub-parts 10, 4, 1 and 2a of figure 3 (referred to as figures 10, 4, 1 and 2a by the Examiner) show a retention pin. None of sub-parts 10, 4, 1 and 2a of figure 3 show first and second cortical bone portions. And none of sub-parts 10, 4, 1 and 2a of figure 3 show an assembled implant.

Moreover, sub-parts 1 and 2a of figure 3 do not even depict dowels as asserted by the Examiner. Sub-parts 1 and 2a of figure 3 illustrate sutures tying the Albee implant to the broken bones of a patient.⁸ The suture is illustrated by the knots on the left side of each illustrated suture.⁹

The Examiner asserts that “circular through holes” are disclosed in the Albee reference, stating that:

Regarding “circular through holes”, a round dowel infers a circular hole...It is the Examiner’s position that the circular holes of Albee extend completely through a portion of the first and second portion, for example, the hip of figure 10. It is noted that figure 2a shows the pins completely through the bone portions as does that shown in figure 15.¹⁰

⁶ Claim 111, Claims Appendix submitted with Appellants’ Brief filed March 12, 2007.

⁷ Examiner’s Answer dated March 11, 2008, pg. 8.

⁸ Exhibit 17, at p. 179, Evidence Appendix submitted with Appellants’ Brief filed March 12, 2007.

⁹ Exhibit 17, at p. 179, Evidence Appendix submitted with Appellants’ Brief filed March 12, 2007.

¹⁰ Examiner’s Answer dated March 11, 2008, pg. 8.

Sub-figures 10, 2a and 15 do not show an assembled implant comprising two cortical bone sections. Since they do not show two cortical bone sections of an assembled implant, they cannot possibly show through holes through those sections.

Moreover, as discussed above, sub-figure 2a shows sutures holding the implant in place, rather than round dowels. Since sub-figure 2a does not show a “round dowel”, one cannot infer “a circular through hole” as the Examiner asserts.

Similarly, sub-figure 15 does not show an implant made of bone, as asserted by the Examiner. It shows an example of a type of joint made from wood. Figure 3 is captioned “The fine joinery element in bone surgery – a group of self-evident analogies.¹¹ Certain sub-figures of figure 3, such as sub-figure 15, illustrate various joints in wood. Figures in the Albee reference that illustrate joints made of wood do not anticipate the assembled bone implant recited in pending claim 111.

Sub-figure 10 does not show through holes through the first and second cortical bone portions of an assembled implant. Sub-figure 10 illustrates a circular peg graft inserted through one bone of a patient and into another bone. The holes illustrated in sub-figure 10 of the Albee reference are not within components of an implant, but rather they are within the patient’s bones.

2. The Albee Reference Does Not Anticipate Pending Claim 112

Pending claim 112 is directed to an assembled bone implant wherein the “first cortical bone portion and said second cortical bone portion each have a D shape.”¹² Pending claim 112 is not anticipated by the Albee reference because the Albee reference does not disclose first and second cortical bone portions having a D shape.

The Examiner has asserted that sub-figures 1 and 2a in figure 3 of the Albee reference “teach long bones such as the tibia which inherently have a D shaped cross-section as evidenced

¹¹ Exhibit 17, at p. 179, Evidence Appendix. (Emphasis added).

¹² Claim 112, Claims Appendix submitted with Appellants’ Brief filed March 12, 2007.

by at least figure 7 of Stroever et al (5,728,159)".¹³ However, the cross section of a long bone as shown in sub-figures 1 and 2a is a bone into which the implant is inserted, not the implant itself.

3. The Albee Reference Does Not Anticipate Pending Claims 116, 131 and 136

Pending claim 116 is directed to an assembled implant wherein the "first cortical bone portion is a mirror image of said second cortical bone portion."¹⁴ Pending claims 131 and 136 are directed to assembled bone implants having "stacked" first and second cortical bone portions.¹⁵ Pending claims 116, 131 and 136 are not anticipated by the Albee reference because the Albee reference does not disclose first and second cortical bone that are stacked or mirrored.

The Examiner has asserted that sub-figure 10 in figure 3 of the Albee reference shows first and second cortical bone portions which are "stacked" and "mirrored".¹⁶ As discussed above, sub-figure 10 does not show first and second cortical bone portions of an assembled implant. Sub-figure 10 illustrates a circular peg graft inserted through one bone of a patient and into another bone. The two bones are not first and second cortical bone portions of an assembled implant. Since sub-figure 10 does not show first and second cortical bone portions, it cannot show "stacked" or "mirrored" first and second cortical bone portions.

4. The Albee Reference Does Not Anticipate Pending Claim 121

Claim 121 is directed to an assembled implant "sized and shaped in the form of a cervical implant."¹⁷ Pending claim 121 is not anticipated by the Albee reference because the Albee reference does not disclose an assembled implant sized and shaped in the form of a cervical implant.

¹³ Examiner's Answer dated March 11, 2008, pgs. 8-9.

¹⁴ Claim 116, Claims Appendix submitted with Appellants' Brief filed March 12, 2007.

¹⁵ Claim 131 and 136, Claims Appendix submitted with Appellants' Brief filed March 12, 2007.

¹⁶ Examiner's Answer dated March 11, 2008, pg. 9.

¹⁷ Claim 121, Claims Appendix submitted with Appellants' Brief filed March 12, 2007.

The Examiner has relied upon sub-figures 2a and 10 of figure 3 of the Albee reference as being “in the form of a cervical implant”.¹⁸ Sub-figures 2a and 10 do not relate to cervical implants. The Examiner admitted that sub-figure 2a is a “long bone such as the tibia” and sub-figure 10 is a “hip”.¹⁹ Thus, the Examiner committed a factual error in asserting that the figures relate to cervical implants.

5. The Albee Reference Does Not Anticipate Pending Claim 122

Pending claim 122 is directed to an assembled implant “having a height between 7 and 14 mm.”²⁰ The Examiner has conclusorily asserted that “a first and second bone portion can be selected to meet the sizing.”²¹ The Examiner has not identified any portion of the Albee reference that is purported to teach the limitation added in dependent claim 122.²²

B. The Coates Reference In View of the Siebels Reference Does Not Render the Claims 111-118 and 120-136 Obvious, and the Rejection Under 35 U.S.C. §103(a) Should Be Withdrawn

1. The Combination of Coates and Siebels Does Not Teach All Of The Elements of Claim 122

Claim 122 recites an assembled implant having “a height between 7 and 14 mm.”²³ The pending obviousness rejection of pending claim 122 is improper because Coates and Siebels, either alone or in combination, do not teach this element. The Examiner has cited column 11, lines 62 et seq. of Coates as support for the rejection of claim 122.²⁴ Coates teaches a spacer, as

¹⁸ Examiner’s Answer dated March 11, 2008, pg. 9.

¹⁹ Examiner’s Answer dated March 11, 2008, pg. 8.

²⁰ Claim 122, Claims Appendix submitted with Appellants’ Brief filed March 12, 2007.

²¹ Examiner’s Answer dated March 11, 2008, pg. 9.

²² Examiner’s Answer dated March 11, 2008, pg. 9.

²³ Claim 122, Claims Appendix submitted with Appellants’ Brief filed March 12, 2007.

²⁴ Examiner’s Answer dated March 11, 2008, pg. 11.

opposed to an assembled implant, having a height of “about 7 mm”.²⁵ An assembled implant having a height between 7 and 14 mm is not taught by a spacer having a height of about 7 mm.

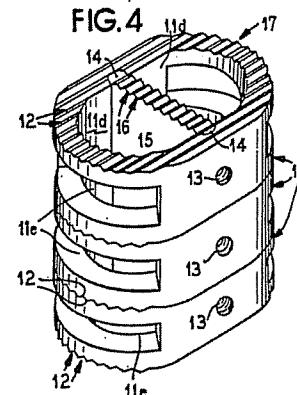
C. The Brantigan Reference In View of the Coates Reference Does Not Render the Claims 111-118 and 120-136 Obvious, and the Rejection Under 35 U.S.C. §103(a) Should Be Withdrawn

1. A Combination of Brantigan and Coates Does Not Teach Each and Every Element of Pending Independent Claim 126

Applicant would like to address a point about claim 126. Pending independent claim 126 recites a D-shaped assembled bone implant having a through-hole sized and positioned for receiving a retention pin.²⁶ The Examiner has pointed out that claim 126 “does not require a circular through hole.”²⁷ This is correct. However, the Brantigan reference does not illustrate through holes or retention pins that are of appropriate diameter for fitting said through holes.

Figures 1-5 of the Brantigan reference illustrate the embodiments referenced by the Examiner with respect to elements 14 and 24, as well as “the entire opening” which corresponds to central apertures 11d and 21d. As an example, Figure 4 is shown at right. Elements 14, which correspond with elements 24, are grooves in the side walls of the interior faces of the Brantigan implants, and are not though holes as recited in pending claim 126. The Brantigan reference describes elements 14 and 24 as “upstanding open ended vertical grooves.”²⁸

The Examiner has apparently recognized that the grooves of



²⁵ Exhibit 18, Evidence Appendix submitted with Appellants’ Brief filed March 12, 2007.

²⁶ Claim 126, Claims Appendix submitted with Appellants’ Brief filed March 12, 2007.

²⁷ Examiner’s Answer dated March 11, 2008, pg. 12.

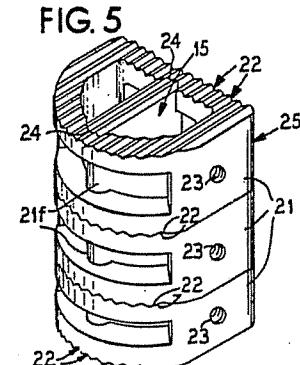
²⁸ Exhibit 20, at Col. 4, lns 23-25, Evidence Appendix submitted with Appellants’ Brief filed March 12, 2007. (Emphasis added).

Brantigan are not through holes, and has therefore asserted that “the entire opening can be interpreted as the through hole.”²⁹ Central apertures, as shown above in Figure 4 as 11d, of Brantigan are also not through holes sized and positioned for receiving a retention pin.

2. A Combination of Brantigan and Coates Does Not Teach Each and Every Element of Pending Independent Claim 129

Pending independent claim 129 recites an assembled bone implant comprising first and second cortical bone portions and “one or more pins of appropriate diameter” for connecting said cortical bone portions.³⁰ Even if the Brantigan and Coates references are combined, the combination does not teach the element of “one or more pins of appropriate diameter” as recited in claim 129.

The Examiner has taken the position that “elements 14 and 24 are semi-circles which have a diameter” and “pin 15 can be described as having an appropriate diameter, the diameter of the elements 14, 24.”³¹ The connecting bars of Brantigan are not retention pins of appropriate diameter for fitting said through holes as recited in claim 129. Brantigan discloses that the “grooves are provided for mounting a rectangular connecting bar 15 shown in FIG. 3.”³² Figure 5 of Brantigan, shown at right, illustrates that the ends of rectangular connecting bar 15 fit into semi-circular grooves 24, but that the main body of the rectangular connecting bar traverses the width of the central aperture between the grooves 24 on either side of the central aperture. The rectangular connecting bar thus extends beyond the grooves 24, and thus is not “of appropriate diameter for fitting said through holes” if the grooves are interpreted as being



²⁹ Exhibit 15, at p. 5, Evidence Appendix submitted with Appellants’ Brief filed March 12, 2007.

³⁰ Claim 126, Claims Appendix submitted with Appellants’ Brief filed March 12, 2007.

³¹ Examiner’s Answer dated March 11, 2008, pg. 12.

³² Exhibit 20, at Col. 4, lns 25-29, Evidence Appendix submitted with Appellants’ Brief filed March 12, 2007. (Emphasis added).

through holes. Furthermore, the rectangular connecting bar traverses a portion of the central aperture, but does not fill the space defined by the central aperture, and is thus not "of appropriate diameter for fitting said through holes" if the central aperture is interpreted as being a through hole.

CONCLUSION

In view of the arguments and evidence provided herein by the Appellants, all bases for the rejection of claims 111-118, 120-123 and 129-136 under 35 U.S.C. § 102(b) in view of Albee, the rejection of claims 111-118 and 120-136 under 35 U.S.C. § 103(a) with respect to Coates in view of Siebels, and the rejection of claims 111-118 and 120-136 under 35 U.S.C. § 103(a) with respect to Brantigan in view of Coates have been rebutted. For these reasons, the Appellants respectfully request the withdrawal of all bases for rejection and the allowance of pending claims 111-118, and 120-136.

Appellants believe that no fee is currently due under 37 C.F.R. §41.20(b)(2) in conjunction with the filing of this reply brief. The Commissioner is authorized to charge any additional fees that may be due, or to credit any overpayment, to account number 13-0017, in the name of McAndrews, Held & Malloy, Ltd.

Dated: May 12, 2008

Respectfully submitted,

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